

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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15pm

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 7, 2001, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail at SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss single patient use of nonapproved oncology drugs and biologics. This is a continuation of the discussion started at the December 13 and 14, 2000, meeting.

Procedure: The meeting is open to the public from 8 a.m. to 1 p.m. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 31, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should

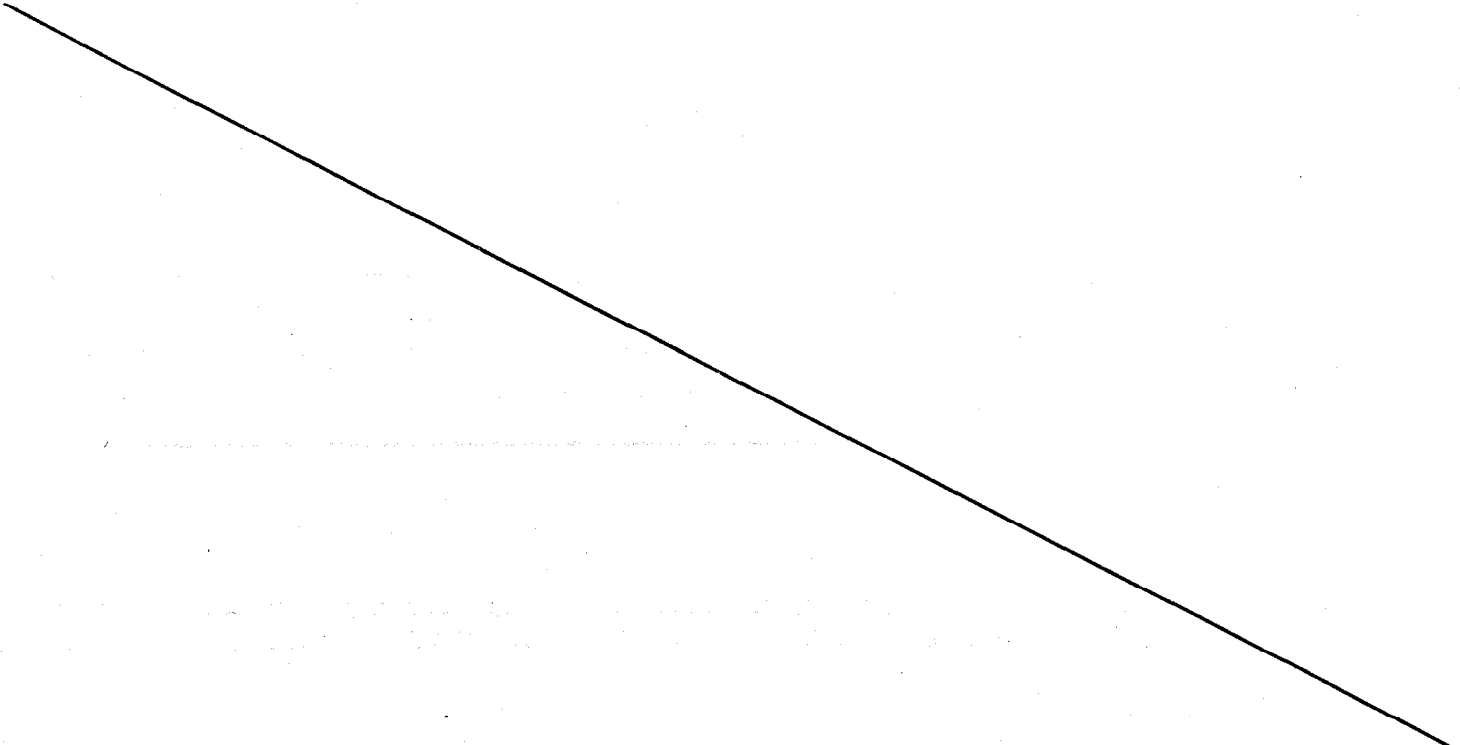
notify the contact person before May 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Background materials for this meeting will be posted at the Oncologic Drugs Advisory Committee dockets Web site at www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to the Oncologic Drugs Advisory Committee meetings.) The slides and transcripts from the meeting will be posted at this same Web site about 3 weeks after the meeting.

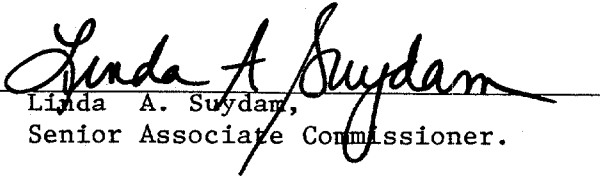
Closed Committee Deliberations: The meeting will be closed from 1 p.m. to 5:30 p.m. to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

FDA regrets that it was unable to publish this notice 15 days prior to the May 23, 2001, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Dated: May 22, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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